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# STATE OF DELAWARE **DEPARTMENT OF STATE**

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**DIVISION OF PROFESSIONAL REGULATION** 

PUBLIC MEETING NOTICE: BOARD OF PHARMACY

DATE AND TIME: Wednesday, April 21, 2010 at 9:30 a.m.

PLACE: Conference Room 1st floor, Cannon Building

861 Silver Lake Blvd., Dover, DE

APPROVED: May 19, 2010

## **MEMBERS PRESENT**

Sandra Robinson, R.Ph, Professional Member, President Howard Simon, R.Ph, Professional Member Don Holst, R.Ph, Professional Member Joli Martini, R.Ph, Professional Member David Bonar, Public Member David W. Dryden, R.Ph., J.D., Executive Secretary

## **MEMBERS ABSENT**

Geoffrey N. Christ, Esq., R.Ph, Professional Member, Vice President Sebastian Hamilton, R.Ph, Professional Member Michael Hertzfeld, Public Member Carolyn Calio, Public Member

# **DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT**

Allison Reardon, Deputy Attorney General Nancy Fields, Administrative Specialist II James Kaminski, R.Ph., Pharmacist Administrator

## **ALSO PRESENT**

Trent Beach
Brandon Nolte
Jeffrey Lentowski
Suzanne Raab-Long
John Casalino
Scott Samples
Cheryl Heiks

#### **CALL TO ORDER**

Ms. Robinson called the meeting to order at 9:33 a.m.

#### **REVIEW OF MINUTES**

A motion was made by Mr. Bonar, seconded by Mr. Holst, to approve the minutes as amended. The motion unanimously carried.

## PRESIDENT'S REPORT

On March 25, 2010, Ms. Robinson attended the Drug Disposal Committee meeting at Governor Bacon Health Center.

On April 15, 2010, Ms. Robinson attended the Controlled Substance Sub-Committee meeting for statutory review at Governor Bacon Health Center.

On April 15, 2010, Ms. Robinson attended the Controlled Substance Sub-Committee meeting for Regulatory review at Governor Bacon Health Center.

# **UNFINISHED BUSINESS**

### Legitimate Medical Purpose

There was no report.

## Drug Disposal and Distribution Review

Ms. Robinson advised that there will be a Drug Disposal program at Beebe Hospital in Sussex County, Kent General Hospital in Kent County and at the New Castle Police Department in New Castle County.

The proposed shredder program was denied. Ms. Reardon is reviewing the details.

# Regulation 14 Review - Administration of Injectable Medications

There was no report.

#### Prescription Monitoring Program (PMP)

Mr. Dryden advised the Board that Governor Markell introduced the PMP program and the grant was requested and are in the beginning stages of draft legislation.

Mr. Bonar stated that there are links for the available grants on the internet and the public can subscribe to the grant service.

# Regulation 7 Review

No report at this time but the Committee will be setting up a time for another meeting.

## Review of State of Emergency

Mr. Dryden sent a letter to DEMA and shared DEMA's response with the Board. Mr. Turner and Mr. Ellis both felt that pharmacists do not meet the medical/health standards of 20 Del. 3116 since pharmacies are not a subdivision and not subjected to the requirements. He also advised that there is a workgroup refining the travel restrictions and it is strongly encouraged to consider the development of an emergency and continuity of operations plan. Mr. Dryden suggests meeting with officials to come up with solutions together.

#### **NEW BUSINESS**

#### Pharmacist-In-Charge (PIC) Interviews

Marie Meyers was unable to attend today; therefore, her interview was tabled and she will be put on next month's agenda. No other PIC interviews were conducted.

## Ratification of Pharmacist Licenses

A motion was made by Mr. Holst, seconded by Mr. Simon, to ratify the licensures issued by the Division of Professional Regulation for the following individuals:

Nicza Perez-Morales Harini Pappu Latoya J. Kennedy Kathleen T. Smith Raidah J. Salem Frederica M. Guillaume-Coupet Lucilla C. Akanegbu Jeffrey A. Timmerman Lucy Somer

The motion was unanimously carried.

#### Pharmacist/Pharmacies Application Reviews

Xttrium Laboratories' application was reviewed by the Board because they have a history of a disciplinary action in other states. The documentation shows that the Pharmacy is still on probation in Missouri for unlicensed distribution.

A motion was made by Mr. Holst, seconded by Mr. Bonar, to table their application until documentation is received that proves that their probation period is over. The motion unanimously carried.

Mr. Dryden will forward correspondence to Xttrium Laboratories advising them of the Board's decision.

#### Pharmacist Consultant Interviews

There were no consultant interviews.

## Proposed Regulations Hearing – Sections 1,5,9,10, and 19

Ms. Reardon stated that the purpose of the hearing was to adopt the rules and regulation amendments. The exhibits including one written comment from Angelo Chiari, R.Ph. was read to the Board. The Board was introduced. Ms. Robinson called for public comment. Being no public comment, the Board closed the public hearing.

A motion was made by Mr. Bonar, seconded by Ms. Martini, to go off the record for deliberations. The motion unanimously carried.

After a short deliberation period, a motion was made by Mr. Bonar, seconded by Mr. Holst to go back on the record. The motion unanimously carried.

A motion was made by Mr. Bonar, seconded by Ms. Martini, to accept the proposed regulations as written. The motion unanimously carried.

## Consent Order – Francis D'Allura

After review, a motion was made by Mr. Bonar, seconded by Mr. Holst, to accept the consent agreement as written. Mr. Simon abstained. The motion carried.

## **Committee Reports**

Joint Practice Committee - Don Holst and Howard Simon - No report.

**Physician's Assistant Report – Sebastian Hamilton, R.Ph:** - Mr. Hamilton informed the Board via report that the council met on Tuesday, April 6, 2010. The council approved four new applications for licensure, four applications for controlled prescriptive authority, and one application for non-controlled prescriptive authority. The next meeting is scheduled for Tuesday, May 4, 2010.

Newsletter – Sandy Robinson, R. Ph., David Dryden, R.Ph., J.D, and Joli Martini, R. Ph.: Mr. Dryden asked the Board members to submit their ideas for new articles.

Legislative – Sandy Robinson, R.Ph, Howard Simon, R.Ph, Sebastian Hamilton, R.Ph, Don Holst, R.Ph, Geoffrey Christ, R.Ph., Esq., and David Dryden, R.Ph., J.D.: On April 18 Ms Robinson provided information to Rep Carson regarding the wording change for Title 16.

On April 20, 2010 Rich Dennis of Delaware State Police met with Rep Carson regarding some possible language changes to HB 235.

Continuing Education – Sandy Robinson, R. Ph., Michael Hertzfeld, Geoffrey Christ, R.Ph., Esq., and Joli Martini, R. Ph.: No report.

Consumer Affairs – Carolyn Calio, Michael Hertzfeld, and David Bonar: No report.

**Professional Liaison – Sandra Robinson, R.Ph. and Joli Martini, R.Ph:** Ms. Robinson announced that Ms. Martini will replace Mr. Holst on this committee.

Ms. Robinson reported that the Delaware Pharmacists Society (DPS) is sponsoring a program on April 29, 2010 at Harry's Savoy Grille in Wilmington at 6:30 p.m.

Registration forms for the DPS Convention on May 12, 13, & 14, 2010 can be submitted online or by mail.

The Delaware Society of Health-System Pharmacists (DSHP) is sponsoring a medical education program entitled "Helping to Prevent Disease in Appropriate Adults through Vaccination". One session is scheduled for Thursday, April 22, 2010 at 6:00 p.m. at the Nage in Rehoboth and the second session is on Thursday, April 29, 2010 at 6:30 p.m. at the White Clay Creek Country Club.

DSHP's Annual Spring Banquet is scheduled for tonight, Wednesday, April 21, 2010 at 6:00 p.m. at the White Clay Creek Country Club at Delaware Park. Pharmacists will receive one CE credit for attending.

**MPJE Study Committee – Don Holst, R.Ph, Sebastian Hamilton, R.Ph, and James Kaminski:** Mr. Kaminski stated that he and Mr. Hamilton attended the National Association of Boards of Pharmacy (NABP) Multistate Pharmacy Jurisprudence Examination (MPJE) Itemwriting Workshop, held April 8 - 9, 2010, at NABP Headquarters in Mount Prospect, IL. The majority of the workshop was devoted to writing test questions. Each state was asked to write 25 questions for the MPJE item pool. This goal was surpassed.

In addition, the format process of the test taken by pharmacist licensure candidates has changed. There are still 90 questions, but instead of 60 questions being scored out of the 90

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questions, now 75 questions are being scored. A new item format for newly written MPJE items was being considered; therefore, some questions submitted were requested to be in the new format. The format would be to select **ALL** the correct answers.

The Board had concerns with the "all correct answer" format. After discussion the Board requested that Mr. Dryden contact NABP and voice their concerns and inform NABP they did not wish to use this format for the Delaware MPJE test.

Controlled Substance Liaisons – Geoffrey Christ, Howard Simon, and Dave Dryden: The tamper proof prescription pad, PMP, drug disposal, and Title 16 are all in the legislation process.

Mr. Dryden reported that the Committee is working on language for Regulations 3.1.4 and 4.2.2 regarding ID's and other security issues such as camera surveillance, back-up power, etc. as well as the 7-day schedule II and III expiration issue.

Substantially Related Crimes Committee - Geoffrey Christ, Howard Simon, Allison Reardon, and Dave Dryden: No report.

## **Board Correspondence**

Mr. Dryden read a memo from CVS Caremark dated March 24, 2010 regarding Delaware patient prescriptions.

## **Inspection Report**

Inspections were conducted at seven pharmacies, eleven Controlled Substance Authority, six medical gas dispensers, two clinics, two practitioners and two researchers. During the inspection process of medical gas dispensers, some facilities in Delaware are just storing oxygen for delivery. Patient records are kept and processing of orders is done at central location, which in some instances the location is out of state. Some facilities that do not employ a licensed healthcare professional, receive verbal orders that are followed by a facsimile or written prescription prior to dispensing.

When deficiencies are found during the inspection process or audits of controlled substances are not acceptable, the office requires written responses from the pharmacist-in-charge (PIC) or notifies the facility that a re-inspection will occur. There are four outstanding requests for a response at present. Three facilities are on hold for re-inspection.

Under current requirements, pharmacist were being asked to verify the identification of the bearer and receiver of the controlled substance prescription by reference to valid photographic identification and record the unique number associated with the valid photographic identification as part of the prescription record for prescriptions written by non-resident practitioners and resident practitioners.

The old regulation **I.** stated "The pharmacist or an employee under his/her supervision must verify the identity of the person receiving a dispensed controlled substance at the time it is transferred to that person. A driver's license or a similar document containing a photograph and the name and address of the person is an acceptable document. The name and address of the person should be recorded on either the prescription or patient's profile. The pharmacist or employee is not required to follow this procedure for each transaction if the identity of the person is clearly established by visual recognition. In those cases, the information shall be recorded at least once."

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## Other Business before the Board

Mr. Christ, Mr. Holst, and Mr. Dryden will be attending the Annual NABP meeting in May.

## **Public Comments**

A representative from CVS brought the blue prints of their new store to turn in to Mr. Dryden.

John Casalino advised that he had some ideas on how to implement the emergency and said that hospital and community Pharmacists should be given priority a plan such as using SUVs for the pharmacy and hospital employees.

# **Next Scheduled Meeting**

The next meeting is scheduled for May 19, 2010 in Conference Room A.

# **Adjournment**

A motion was made by Mr. Holst seconded by Mr. Simon to adjourn the meeting. The motion unanimously carried. The meeting adjourned at 11:00 a.m.

Respectfully submitted,

Nancy Fields

Manay Lields

Administrative Specialist II